

PATIENT CHOICE and MEANINGFUL DISCLOSURE WORK GROUP PROJECT CHARTER

KEY TERMS

Patient "Opt-Out" Choice: Patient "opt-out" refers to the consent policy adopted by the Illinois Health Information Exchange (ILHIE) Authority for the exchange of patient information through the ILHIE. It allows patient health records maintained by health care providers and institutions participating in the ILHIE to be automatically accessible through the ILHIE unless a patient "opts-out," that is, exercises his or her choice to deny access to all such information through the exchange.

- If patients do not exercise the right to opt out, their clinical data can be transmitted through the ILHIE. A patient can elect to opt out or revoke the opt-out choice (that is, opt back in) at any time. If a patient opts out of the ILHIE, patient data can be sent by secured email, fax or U.S. Mail.
- Right now, only general medical and mental health information is subject to patient "opt-out". Specific patient
 consent must be sought by substance use treatment information, HIV testing and genetic testing, none of which
 can be sent through the ILHIE until federal and state laws are amended.

Meaningful Disclosure: Meaningful disclosure is the process and the content of the process by which patients and recipients are educated and informed by their providers at the point of care about health information exchange (HIE), how and with whom their PHI will be shared in or through an HIE and their rights to expressly decline any further disclosure of their PHI by an HIE to third parties so as to make a meaningful and informed decision about whether or whether not to participate in an HIE.

WORK GROUP DIRECTIVE

This Work Group will define the scope of patient opt-out consent and identify and recommend a set of appropriate rules, standards and data sharing provisions that the ILHIE and participants to the ILHIE shall adopt and implement to meet the statutory requirement that each patient or recipient whose record is accessible through an HIE shall be provided a reasonable opportunity to expressly decline the further disclosure to third parties of PHI by health information exchange, except to the extent permitted by law, and to revoke a prior decision to opt-out or decision not to opt-out.

This Work Group will define the scope and content of meaningful disclosure for HIE in Illinois, identify and recommend issues and topics that should be addressed by providers at the point of care and develop tools, materials and other resources for use by providers to ensure that patients and recipients receive meaningful disclosure at the point of care about HIEs and their rights with respect to the disclosure of their PHI by an HIE to third parties.

DELIVERABLES

- HIE policies and procedures establishing best practices for patient opt-out consent management;
- Template patient opt-out and revocation forms for use by providers at the point of care; and
- Regulatory language for use in the administrative rule making process around the issue of patient opt-out choice.
- HIE policies and procedures establishing best practices for meaningful disclosure to patients;
- Template language for Notices of Privacy Practices or other deliverables to be given to patients and recipients by
 providers at the point of care around the issues of opt-out consent and meaningful disclosure such as a potential
 acknowledgement of receipt of meaningful disclosure, brochures or other written notice of a patient's or



- recipient's right to opt-out of an HIE, which directs the person to an HIE website containing an explanation of the purposes of the HIE and audio, visual and written instructions on how to opt-out of participation.
- Recommendations for HIE website content and audio, visual and written instructions regarding how to opt-out
 of participation in an HIE.
- Regulatory language for use in the administrative rule making process around the issue of meaningful disclosure to patients.

MAJOR ACTIVITES

- Teleconferences with and data collections from ILHIE participant entities with respect to their consent models, policies, forms and the content of their disclosures;
- Comprehensive data collection of consent policies, forms and disclosures from other States utilizing an Opt-Out Consent model;
- Comprehensive review of materials and information gathered from ILHIE participant entities and survey of optout Statewide HIEs;
- Identification of "best practices" to be incorporated into ILHIE policies, forms and disclosures;
- Drafting, discussion and revision of ILHIE's proposed policies, forms and disclosures.

TIMELINE

- July/Aug/Sept 2013 Data Security & Privacy Committee and Regional HIE Work Group meetings and approvals
 of ILHIE's proposed policies, forms and disclosures
- Sept 2013 Status report to the ILHIE Authority Board
- Nov 2013 ILHIE's proposed policies, forms and disclosures (Work Group deliverables)

WORKSHOP HANDOUTS

- A template document outlining the policy issues and recommendations underlying the form and content of ILHIE's proposed policies, forms and disclosures;
- Exemplary forms and content from surveys of ILHIE participants and Opt-Out State policies, forms and disclosures;
- ILHIE's proposed policies, forms and disclosures.

STAKEHOLDER ROLE

- Collaborate with ILHIE Authority staff, Work Group members and other stakeholders in carrying out the Work Group's directives and in meeting its major activity objectives.
- Lending each stakeholder's unique perspective, knowledge, training and experience to the task of creating the ILHIE's standards and policies around Patient "Opt-Out" Choice and Meaningful Disclosure.
- Attend Work Group meetings and undertake tasks assigned by the Work Group Co-Chairs until such time as the Work Group's major activity objectives have been achieved.



Patient Choice and Meaningful Disclosure Work Group: Meaningful Disclosure at the Point of Care Subgroup

July 24, 2013 10:00 a.m. – 12:00 p.m. James R. Thompson Center¹ 100 W. Randolph Street Chicago, Illinois 60601

Action Plan

Co-Leaders: Marcia Matthias

TBD

Objectives: Define the scope of patient opt-out choice at the point of care and make a set of

policy recommendations that HIEs and their participants will implement to meet the statutory requirement that every patient whose health record is accessible through a HIE shall be provided a reasonable opportunity to expressly decline the further disclosure of their PHI by the HIE, except to the extent permitted by law,

and to revoke their prior decision to opt-out or not opt-out of a HIE.

Define the scope and content of meaningful disclosure regarding HIE at the point of care, identify issues about HIE that should be addressed at the point of care and develop resources for use by providers at the point of care to ensure that patients receive meaningful disclosure about HIE and their rights with respect to the disclosure of their PHI by means of HIE to other providers or third parties.

Deliverables: Policy Recommendations for Patient Choice and Meaningful Disclosure at the

Point of Care

Statutory Notice Required under HB1017

Recommendations for Amendments to Notice of Privacy Practices

Opt-Out Form and Revocation of Opt-Out Form

Resources²: ILHIE Authority Data Privacy and Security Committee Report (09/19/12)

HB1017 Amending the Mental Health and Developmental Disabilities

Confidentiality Act

Multi-State HIE Opt-Out Survey Resources (zip file) Patient Choice and Meaningful Disclosure Policy Draft

¹ For those unable to attend the meeting in person, there will be call-in numbers for the Work Group's plenary session and each subgroup's break-out session.

² Resources are available at: http://www2.illinois.gov/gov/HIE/Pages/PCMDWorkGroup.aspx.



1. Collection of patient "opt-out" at provider point of care

Preference: The provider at the point of care is responsible for providing its patient with the opportunity to opt-out, including the distribution, collection and processing of opt-out forms.

a. Frequency of collection

Preference: Once per provider.

b. Duration

Preference: A patient's "opt-out" choice is perpetual until revoked.

c. Documentation

Preference: Provider will distribute, collect and maintain documentation of a patient's opt-out preference, including any written consents as may be required for "specially protected" patient health information, in accordance with the provider's own policies for the collection and maintenance of patient opt-out preferences. It is anticipated that the ILHIE Authority, through its Patient Choice and Meaningful Disclosure Work Group, will facilitate the creation of template forms for distribution and use by providers in documenting patient opt-out preferences.

d. Transmission to ILHIE

Preference: An ILHIE participant will send an electronic message (IHE standard) notifying the ILHIE of a patient's decision to opt-out, triggering an "electronic flag" for that patient in the ILHIE's Master Patient Index (MPI). If the ILHIE participant's system is unable to send an electronic message in the prescribed IHE standard, the provider will have access to a secure website that will enable the entry of a patient's opt-out decision into the ILHIE's MPI.

e. Reconciliation

Preference: The last in time (i.e., the most current) consent preference on record with the ILHIE will govern all disclosure of information by the ILHIE for any particular patient.

f. Revocation

Preference: A patient may elect to revoke a prior opt-out, that is, opt back in to the ILHIE at any time by requesting that any of his or her ILHIE-connected providers reverse the patient's last recorded opt-out choice. The provider will send an electronic message (IHE standard) or use the



provider website provided by the ILHIE to notify the ILHIE of the patient's updated preference, thus reversing the consent flag for that patient in the ILHIE's MPI.

2. Collection of patient "opt-out" at HIE

a. Storage at HIE

Preference: The ILHIE will maintain its MPI as a central registry of patient consent preferences. The ILHIE will not collect or store opt-out forms, which documentation will be collected and maintained by a patient's provider at the point of care in accordance with the provider's own policies for the collection and maintenance of patient opt-out preferences.

b. Patient Access

Preference: Currently, there is no electronic patient portal for the communication and receipt of a patient's opt-out consent preference at the level of the ILHIE. The ILHIE Authority will consider the feasibility of enabling this functionality, including concerns regarding the authentication of individuals.

c. Revocation

Preference: The ILHIE will maintain its MPI as a central registry of patient consent preferences. Initially, access to the ILHIE's MPI will be available to providers participating in the ILHIE. Direct patient access to ILHIE's MPI for the management of their own consent preference may be made available at a future date. The ILHIE will not collect or store revocation of opt-out forms, which documentation will be collected and maintained by a patient's provider at the point of care in accordance with the provider's own policies for the collection and maintenance of patient opt-out preferences.

3. Data filtering triggered by "opt-out"

a. At Provider EHR

Preference: Providers who have received a patient's opt-out preference will honor this preference and ensure that notice of a patient's opt-out has been communicated to the ILHIE.

b. At ILHIE

Preference: The ILHIE's MPI will be the central registry of patient opt-out preferences in Illinois. All HIEs in Illinois will use ILHIE's MPI as the single source of information for applying patient consent preferences when handling patient data so that the opt-out choice applies to all providers. When a request comes in from a provider to the ILHIE for the purpose of obtaining an aggregated report about a particular patient, the MPI flag will be queried. If the patient has exercised an opt-out, an aggregated document will not be transmitted. Instead, consistent with the patient's reasonable expectations, a message will be sent to the requesting provider that there is "no information available."



c. At Regional HIEs

Preference: The ILHIE Authority, in collaboration with the Regional HIEs, will evaluate and identify mechanisms for ensuring that patient consent preferences are accurately and consistently applied and recognized across all HIEs in Illinois.

4. Data filtered by "opt-out"

a. Global

Preference: Data filtering as a result of a patient opt-out is global, meaning all data from all sources available through the ILHIE will be unavailable for disclosure, except as permitted by law, such as in the case of public health reporting.

5. Meaningful Disclosure at Provider Point of Care

Preference: The provider at the point of care is responsible for providing its patients with meaningful disclosure, including the distribution of a provider's Notices of Privacy Practices containing a description of the ILHIE and opt-out choice. Providers will provide patients with meaningful disclosure at the patient's first encounter with a provider who has become a participant in the ILHIE. It is anticipated that the ILHIE Authority, through its Patient Choice and Meaningful Disclosure Work Group, will facilitate the creation of template notices, sample language for Notices of Privacy Practices and other materials for distribution and use by providers in providing patients with meaningful disclosure.

a. Content required

Preference: Providers will provide their patient with meaningful disclosure regarding (i) health information exchange (HIE); and (ii) a patient's right to opt-out of disclosure in an HIE. The ILHIEE Authority will have resources available on its website to assist providers in meeting their meaningful disclosure obligations.

b. Form of Disclosure

Preference: Providers will provide patients with written notice, which may be included in the form of a provider's Notice of Privacy Practices, describing health information exchange and a patient's right to opt-out. In accordance with their own policies for meaningful disclosure regarding health information exchange and patient opt-out rights, providers may also provide patients with additional written materials concerning health information exchange and a patient's right to opt-out which directs the patient to a health information exchange website containing (i) an explanation of the purposes of the health information exchange; and (ii) audio, visual, and written instructions on how to opt-out of participation a health information exchange. Providers may also utilize written signs, posters, brochures, pamphlets, website postings, Q&As, audiovisual information and oral briefings to educate patients about health information exchange and patient opt-out rights.



c. Patient Acknowledgement

Preference: Providers may require their patients to execute an acknowledgement of receipt of meaningful disclosure for inclusion in the patient's medical record in accordance with the provider's own policies for meaningful disclosure regarding health information exchange and patient opt-out rights.



Patient Choice and Meaningful Disclosure Work Group: Meaningful Disclosure at HIE Website Subgroup

July 24, 2013 10:00 a.m. – 12:00 p.m. James R. Thompson Center¹ 100 W. Randolph Street Chicago, Illinois 60601

Action Plan

Co-Leaders: Danny Kopelson

TBD

Objectives: Define the scope and content of meaningful disclosure regarding health

information exchange at the level of the HIE website, identify issues about health information exchange that should be addressed on a HIE website and develop resources for consumers at the HIE website and for providers at the point of care to ensure that patients receive meaningful disclosure about health information exchange and their rights with respect to the disclosure of their PHI by a HIE to

other providers or third parties.

Deliverables: Explanation of the Purposes of a Health Information Exchange

Audio, Visual and Written Instructions on How to Opt-Out of a HIE

Additional Resources, e.g., signs, posters, brochures, pamphlets, consumer-facing web content and frequently asked questions, to Educate Consumers about Health

Information Exchange and Patient Opt-Out Rights

Resources²: HB1017 Amending the Mental Health and Developmental Disabilities

Confidentiality Act

Multi-State HIE Opt-Out Survey Resources (zip file) Patient Choice and Meaningful Disclosure Policy Draft

¹ For those unable to attend the meeting in person, there will be call-in numbers for the Work Group's plenary session and each subgroup's break-out session.

² Resources are available at: http://www2.illinois.gov/gov/HIE/Pages/PCMDWorkGroup.aspx.



6. Meaningful Disclosure at HIE

a. Content required

Preference: Each HIE will establish a publicly-accessible website containing (i) an explanation of the purposes of the health information exchange; and (ii) audio, visual, and written instructions on how to opt-out of participation a health information exchange. The explanation will include the HIE's purposes and potential uses, and the fact that the HIE will disclose a patient's health information to participant in the exchange unless the patient elects to opt-out of further HIE disclosure. The instructions will include the procedures to be followed to opt-out of further disclosure by the HIE, except to the extent provided by law.

b. Form of Disclosure

Preference: In addition to their own website content, HIEs may develop for their own purposes and for providers additional written and electronic notices and materials concerning health information exchange and a patient's right to opt-out including signs, posters, brochures, pamphlets, website postings, Q&As and other means to educate patients about health information exchange and patient opt-out rights.



Patient Choice and Meaningful Disclosure Work Group: Specially Protected Health Information Subgroup

July 24, 2013 10:00 a.m. – 12:00 p.m. James R. Thompson Center¹ 100 W. Randolph Street Chicago, Illinois 60601

Action Plan

Co-Leaders: David Carvalho

TBD

Objectives: Define the scope of patient opt-in choice at the point of care for patients with

specially protected health information and make a set of policy recommendations that HIEs and their participants will implement to meet the requirement of Federal and State law with respect to specific categories of specially protected health information in relation to the new requirement for opt-out choice for general

medical and mental health information within the context of HIE.

Define the scope of patient opt-out choice at the point of care with respect to patient requests for restrictions on the disclosure of specific (non-specially protected) health information and make a set of policy recommendations that HIEs and their participants will implement with respect to patient restrictions on the disclosure of non-specially protected health information within the context of

HIE.

Deliverables: Policy Recommendations for the Disclosure of Specially Protected Health

Information within the Context of Health Information Exchange

Policy Recommendations for the Handling of Patient Requests for Restrictions on the Disclosure of Specific (Non-Specially Protected) Health Information within

the Context of Health Information Exchange

Resources²: ILHIE Authority Data Security and Privacy Committee Report (09/19/12) (see

Continuation of "Opt-In" Under Current Laws at p. 7; and Exhibit E, Overview of

Proposed ILHIE Patient Consent Management Policy, II.A.1. Sensitive PHI

Patients, at p. 22)

Multi-State HIE Opt-Out Survey Resources (zip file) Patient Choice and Meaningful Disclosure Policy Draft

¹ For those unable to attend the meeting in person, there will be call-in numbers for the Work Group's plenary session and each subgroup's break-out session.

² Resources are available at: http://www2.illinois.gov/gov/HIE/Pages/PCMDWorkGroup.aspx.



- 4. Data filtered by "opt-out"
 - b. Per Provider

Preference: Providers who have agreed to patient requests for restrictions on the disclosure of specific health information or who have patients with "specially protected" health information under Federal and State law, such as information regarding alcohol and substance abuse treatment, HIV/AIDS testing and genetic testing, will honor those requests and ensure that their EHRs, if capable, will not make such information available through the ILHIE. If a provider's EHR is incapable of ensuring that such information will not be made available through the ILHIE, then the provider instead will require the patient to opt-out of participation in the ILHIE.



Patient Choice and Meaningful Disclosure Work Group: "Break the Glass" (Medical Emergency) Subgroup

July 24, 2013 10:00 a.m. – 12:00 p.m. James R. Thompson Center¹ 100 W. Randolph Street Chicago, Illinois 60601

Action Plan

Co-Leaders: Mark Pellegrino

TBD

Objectives: Define the scope of patient opt-out choice in the case of medical emergency under

Illinois law and make a set of recommendations to clarify applicable Illinois law, whether through adoption of appropriate regulations or the enactment by the Illinois General Assembly, regarding the permitted disclosure of patient health information in the event of medical emergency within the context of health

information exchange. Define the scope of a self-pay patient's right to restrict the disclosure of specific health information to a health plan or health plan's business associate within the

context of health information exchange.

Deliverables: Recommendations for Clarifying Illinois Law with respect to Opt-Out Override

("Break the Glass") in the Case of Medical Emergency within the Context of

Health Information Exchange

Policy Recommendations for Handling a Self-Pay Patient's Right to Restrict Disclosure of Specific Health Information to a Health Plan or a Health Plan's Business Associate within the Context of Health Information Exchange

Resources²: ILHIE Authority Data Security and Privacy Committee Report (09/19/12) (see

Opt-Out Override/Break the Glass, at p.6)

Multi-State HIE Opt-Out Survey Resources (zip file)

¹ For those unable to attend the meeting in person, there will be call-in numbers for the Work Group's plenary session and each subgroup's break-out session.

² Resources are available at: http://www2.illinois.gov/gov/HIE/Pages/PCMDWorkGroup.aspx.



3. Data filtering triggered by "opt-out"

d. Emergency Access ("break-the-glass")

Preference: As the law in Illinois is unclear regarding the permitted disclosure of patient health information in the event of medical emergency without patient consent, the ILHIE Authority's approach to overriding patient opt-out consent ("break-the-glass") will be to seek clarification of applicable Illinois law, whether through the adoption of regulations or the enactment of laws by the Illinois General Assembly. As currently envisioned, a patient may at an emergency point of care agree to a revocation of that patient's prior opt-out choice to enable the release by the ILHIE of that patient's electronic medical record in response to a request from the emergency medical facility.



BREACH RESPONSE PROTOCOL WORK GROUP PROJECT CHARTER

KEY TERMS

Breach response protocol: A breach response protocol defines and sets forth the method used to investigate, notify and mitigate in case of a breach that releases unsecured PHI, specifically in this case the procedures to be used by HIEs and their participants.

WORK GROUP DIRECTIVE

ILHIE Authority Breach Response Protocol to be proposed to the DSPC for recommendation to the ILHIE Authority Board of Directors in an effort to standardize breach response process for all ILHIE Participants.

The Breach Response Protocol Work Group shall consider, provide feedback and recommend amendments to the proposed ILHIE Authority's Breach Response Protocol. The Protocol standardizes breach investigation, notification and mitigation obligations arising from the use of the ILHIE between the ILHIE Authority and all Participants. The finalized Protocol shall be recommended through the ILHIE Authority Data Security and Privacy Committee (DSPC) to the ILHIE Authority Board of Directors. If adopted, the Protocol will be incorporated into Participant data sharing agreements.

DELIVERABLES

• An ILHIE Privacy and Security Policy and Procedure identifying standard ILHIE participant breach response requirements to be incorporated into the ILHIE Authority's Data Sharing Agreement (DSA)

MAJOR ACTIVITES

- Review and discussion of policy
- Revision as necessary
- Proposal, including draft policy to the DSPC

TIMELINE

- July/Aug 2013 Work Group finalization of feedback/amendments
- Mid-Oct 2013 Proposal to the Data Security and Privacy Committee of the ILHIE Authority Board
- Nov 2013 Recommendation to the ILHIE Authority Board
- Nov/Dec 2013 Adoption, publication on website and DSA template modifications

WORKSHOP HANDOUTS

- Draft Privacy and Security Policy and Procedure
- Chart setting forth the basis for key elements of the Privacy and Security Policy and Procedure and comparing the policies and procedures of various entities and states

STAKEHOLDER ROLE

 Solicit feedback and insight from health systems, hospitals, physician practices, regional health information exchanges and patient advocacy groups to provide credibility when applied to all Participants



PATIENT CONSENT PREFERENCES & DATA SECURITY WORK GROUP PROJECT CHARTER

KEY TERMS

Patient consent preferences: Patient consent preferences can be expressed by a patient identifying the PHI the patient is comfortable sharing via the ILHIE in specific circumstances. The policies and technical infrastructure that support patient consent preferences must be consistent with state and federal laws and reasonable in relation to the capabilities of the ILHIE and its participating providers.

Data security: Data security ensures the protection of PHI in electronic format, including ensuring appropriate and authorized access to PHI in an electronic format and the protection of electronic PHI received, created, maintained, in transit and in rest.

Key roles relative to patient consent preferences to transmit PHI via ILHIE:

Patient	Provider	ILHIE
Exercise choice	Register and transmit choice	Register and transmit choice
	Determine purpose of PHI	Transmits PHI

WORK GROUP DIRECTIVE

The Work Group will proceed by first defining the current capabilities of the ILHIE and how these capabilities interact with connected health care service provider sites. We expect to demonstrate one or two potential approaches to protecting patient data privacy based on prototypes that have been developed recently in Illinois by the ILHIE in collaboration with the Strategic Health IT Advance Research Project (SHARP) and at the Substance Abuse and Mental Health Services Administration (SAMHSA). The work group also will establish the current state of segmenting records.

The Work Group will move on to enumerating specific data security concerns that come from specific patient consent preference scenarios. These concerns and scenarios will be mapped to elements of electronic exchange which will allow the Work Group to make concrete recommendations to the Authority on protecting patient data.

DELIVERABLES

- Documentation of the current capabilities of the ILHIE and how these capabilities interact with connected medical practices and other entities
- A summary of the current state of segmenting records
- A list of patient privacy concerns with a representative sample of associated scenarios
- A list of how the above concerns impact or are impacted by electronic exchange through the ILHIE
- Recommendations for how the ILHIE can address the items in 3 above. The recommendations will be prioritized
 according to the scenario and the population impact. The recommendations will be evaluated according to the
 benefits and disadvantages of each scenario and the feasibility for technical implementation. Feasibility must
 address resource requirements, length of time for implementation and scalability.



MAJOR ACTIVITES

- Establish the current capabilities of the ILHIE and EMR systems to manage data segmentation and at what level of granularity
- 2. Explain or educate on EMR products and their capability as it relates to consent.
- 3. How does Meaningful Use impact: medical records, privacy
- 4. Review SAMHSA demo and assessment of SAMHSA strategic direction regarding record/data segmentation
- 5. Review SHARP's prototype
- 6. Identify specific patient consent preference scenarios
- Map elements of identified scenarios to elements of electronic exchange
- 8. Develop recommendations to the ILHIE Authority Board regarding statutory requirement for annual review of the technology to support record segmentation; prioritize according to population impact and technical feasibility

TIMELINE

- Monthly meetings
- Sept/Nov 2013 Progress updates at Authority Board meetings
- Q1 2014 Preliminary recommendations to the Authority Board
- Q2 2014 Final approval by Authority Board (Work Group deliverables)
- June 2014 Proposed annual technology review of feasible technical capabilities to support patient consent preferences

WORKSHOP HANDOUTS

- Summary of the C-CDA (Consolidated-CDA)
 - Describe continuity of care records discussion of CDA, C32, CCDA
 - Different section headings that fall under C32 and CDA
 - Describe basic constraints
- Brief description with links to the following:
 - Presentation/video on HealthShare
 - SAMHSA demo
 - SHARP's protoype
 - Vocabularies
- Proposed mechanism based on current laws

STAKEHOLDER ROLE

- Identify stakeholder concerns regarding patient consent preferences
 - How are these concerns impacted by electronic exchange through an HIE?